

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY  
AVERAGE WHOLESale PRICE  
LITIGATION

MDL 1456

Master File No. 01-CV-12257-PBS

THIS DOCUMENTS RELATES TO:  
ALL ACTIONS

Judge Patti B. Saris

**IMMUNEX CORPORATION'S ANSWER TO  
PLAINTIFFS' AMENDED MASTER CONSOLIDATED CLASS  
ACTION COMPLAINT**

Defendant Immunex Corporation ("Immunex") answers the Amended Master Consolidated Class Action Complaint ("AMCC"), dated as of January 22, 2004, as follows:

The AMCC improperly and repetitively refers to Immunex and other defendants and third parties on a collective basis, failing to plead with requisite particularity allegations against Immunex.

Immunex was acquired by defendant Amgen during this litigation but remains separately incorporated. Immunex is not responsible for the actions of Amgen, and Amgen is not responsible for the actions of Immunex. Amgen has assumed the marketing of Enbrel, and it will answer as to Enbrel and all related activities.

Intentionally ambiguous pleading is improper and insufficient to apprise Immunex in any meaningful sense of the allegations asserted against it. Immunex has nevertheless

attempted to respond to Plaintiffs' allegations to the extent possible under the circumstances. To the extent allegations refer to the knowledge, conduct, or actions of other defendants or entities, Immunex is without knowledge or information sufficient to form a belief as to the truth of those allegations and, on that basis, Immunex denies those allegations. Immunex answers Plaintiffs' allegations on behalf of itself only, even when Plaintiffs' allegations refer to alleged conduct by Immunex and other persons or entities. The AMCC improperly mixes factual allegations with inflammatory rhetoric so as to make it virtually impossible to respond meaningfully. Many of the allegations of the AMCC are vague or conclusory. The AMCC also includes terms that are undefined and susceptible to different meanings. By addressing factual allegations and not pointing out each and every ambiguity or challenging every innuendo or conclusion, Immunex does not admit any of Plaintiffs' interpretations or conclusions. To save space, Immunex will not repeat the above and similar caveats each time they apply.

The AMCC contains purported quotations from a number of sources, many of which are unidentified. Referencing or purporting to summarize a potential item of evidence is not an allegation and does not require an answer. In responding to allegations consisting of quotations, an admission that the material quoted was contained in a document or was uttered by the person or entity quoted shall not constitute an admission that the substantive content of the quote was or was not true at the time the document was created, much less before or after its creation, or that the material is relevant or admissible in this action.

Immunex denies each and every allegation contained in the AMCC, except as specifically admitted, and any factual allegation admitted is admitted only as to the specific facts and not as to any conclusions, characterizations, implications, innuendo, or speculation contained in or suggested by any allegation or the AMCC as a whole. Moreover, Immunex

specifically denies any allegations contained in headings, footnotes, the Table of Contents, and unnumbered paragraphs in the AMCC.

These comments and objections are incorporated, to the extent appropriate, into each numbered paragraph of this Answer. Immunex numbers its answering paragraphs below to reflect the relevant paragraph or paragraphs in the AMCC.

1. Immunex admits that Plaintiffs purport to bring this alleged class action against Immunex and other pharmaceutical companies but otherwise denies each other or different allegation of Paragraph 1. Immunex denies that Plaintiffs are entitled to maintain this action in the manner alleged.

2. Immunex denies the existence of, or its participation in, any "conspiracy" as alleged in Paragraph 2. To the extent the allegations in Paragraph 2 allege a conspiracy between Immunex and "various publishing entities," no response is required because these allegations, which formed the basis of Count I of the AMCC, were dismissed with prejudice by the Court's Order dated February 24, 2004.

3 & 4. As to Paragraphs 3 and 4, Immunex admits that it has manufactured or distributed certain medicines that are covered under Medicare Part B, and that during certain times Congress mandated that Medicare Part B reimbursement be based upon AWP, an industry practice and term of art incorporated by the government as a reimbursement benchmark, and that Medicare Part B medicines are generally administered in a healthcare provider's office. Immunex admits that it reports some pricing information for its medicines to independent pharmaceutical industry publications. Immunex admits that AWP benchmarks published in trade publications can be higher than the prices ultimately paid by providers. Except as specifically admitted and to the extent that any remaining allegations are directed at Immunex, Immunex denies those allegations.

5 & 8. Immunex denies the existence of, and its participation in, any "AWP scheme" or "unlawful agreement" as alleged in Paragraphs 5 and 8, and denies any remaining allegation.

6. Immunex admits that Plaintiffs purport to bring this action as alleged in Paragraph 6, but Immunex denies that Plaintiffs are entitled to maintain this action in the manner alleged. Immunex denies that it "promotes" its drugs on a "fictitious and inflated AWP." Except as specifically admitted and to the extent that the remaining allegations in Paragraph 6 are directed at Immunex, Immunex denies those allegations.

7. Immunex denies the existence of, or its participation in, any "high profit scheme" as alleged in Paragraph 7. Immunex denies that it has "concealed" information regarding the pricing structure for its prescription drugs.

9 & 10. Paragraphs 9 and 10 contain no allegations against Immunex and therefore require no answer from Immunex.

11. Immunex admits that Plaintiffs have filed attachments to the AMCC. Except as specifically admitted and to the extent the allegations in Paragraph 11 are deemed to include allegations against Immunex, Immunex denies them.

12. Because the Court dismissed Count I in its Order dated February 24, 2004, a response is not required for Paragraph 12. To the extent a response is required, Immunex denies the allegations in Paragraph 12 and Count I of the AMCC.

13 – 21. Immunex denies the existence of, or its participation in, any "enterprise," "scheme," or "conspiracy" as alleged in Paragraphs 13 – 21. Immunex admits that Plaintiffs purport to bring this action as a class action, and that Plaintiffs seek relief under Counts II through X as alleged in Paragraphs 13 – 21. Immunex denies that this action can be maintained in the manner alleged, and further denies that Plaintiffs are entitled to relief under

Counts II through X of the AMCC. Except as specifically admitted and to the extent that the remaining allegations in Paragraphs 13 – 21 are directed at Immunex and require a response, Immunex denies those allegations.

22. Immunex admits that this Court has subject matter jurisdiction, subject to the political question and other defenses raised below. Upon information and belief, Immunex admits that this Court has diversity jurisdiction. Except as specifically admitted and to the extent that the remaining allegations in Paragraphs 22 are directed at Immunex and require a response, Immunex denies those allegations.

23. Immunex admits the allegations in Paragraph 23.

24. Immunex admits that venue is proper in this jurisdiction for purposes of the pretrial proceedings as alleged by Plaintiffs in Paragraph 25, but Immunex denies that venue is proper in this jurisdiction for trial or other non-MDL purposes. Immunex denies the existence of, and its participation in, any "fraudulent marketing scheme" as alleged in Paragraph 24. To the extent that the remaining allegations in Paragraphs 24 are directed at Immunex and require a response, Immunex denies those allegations.

25. Immunex admits the allegations in Paragraph 25.

26 – 31. Immunex is without information sufficient to form a belief concerning the accuracy of the allegations of Paragraph 26 – 31 and therefore denies those allegations.

32 – 36. Immunex admits that Plaintiffs VPIRG, WCA, StateWide, CANY, and CCJ purport to bring this action as alleged in Paragraphs 32 – 36 and its subparts, but Immunex denies that these Plaintiffs have standing to bring the alleged action. Immunex is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraphs 32 – 36 and therefore denies those allegations.

37 & 38. Immunex denies the existence of, or its participation in, any "conspiracy" as alleged in Paragraph 38. Immunex denies any and all remaining allegations in Paragraphs 37 and 38 that pertain to it.

39 - 96. To the extent that any allegations in Paragraphs 39 – 96 are deemed to include allegations against Immunex, Immunex denies those allegations.

97. Immunex admits that it became a wholly-owned subsidiary of Amgen, Inc., during the pendency of this litigation and that its principal place of business as of the commencement of the action is Seattle, Washington. Immunex admits that it developed products for the treatment of cancer, asthma, rheumatoid arthritis, inflammatory diseases, infectious diseases, and cardiovascular diseases. Immunex's Annual Reports speak for themselves. Except as specifically admitted, Immunex denies any and all remaining allegations in Paragraph 97.

98. Immunex admits that it manufactured and distributed pharmaceuticals that were administered by Medicare Plan B providers in most if not all states. Immunex admits that, at various points in time, it manufactured or distributed leucovorin calcium, Enbrel®, Novantrone®, Leukine®, and Thioplex®. Immunex denies any and all remaining allegations in Paragraph 97.

99. Immunex admits that it was acquired by Amgen in July 2002. Immunex denies any and all remaining allegations in Paragraph 97.

100 – 132. To the extent that any allegations in Paragraphs 100 – 132 are deemed to include allegations against Immunex, Immunex denies those allegations.

133. Upon information and belief, Immunex admits the allegations in Paragraph 133.

134. Immunex admits that the Medicare Part B program used AWP as a reimbursement benchmark. Immunex denies any and all remaining allegations in Paragraph 134 that pertain to it.

135. Immunex admits that there are several independently produced pharmaceutical industry compendia that periodically publish AWP and other reimbursement benchmarks and prices. Immunex denies any and all remaining allegations in Paragraph 135 that pertain to it.

136. Immunex denies any allegations in Paragraph 136 that pertain to it.

137 – 141. Immunex denies the existence of, and its participation in, any "scheme to generate the profit spread" or any "AWP scheme" as alleged in Paragraphs 137 – 141. Immunex denies any and all remaining allegations in Paragraphs 137 - 141 that pertain to it.

142 – 144. Immunex admits the allegations in Paragraphs 142 – 144.

145. Immunex admits that 42 C.F.R. § 405.517 sets forth the reimbursement methodology for drugs covered by Medicare Part B and is the best evidence of its contents. Immunex is without information sufficient to form a belief concerning the accuracy of the remaining allegations of Paragraph 145 and therefore denies those allegations.

146 & 147. Immunex denies the allegations in the first sentence of Paragraph 146 insofar as it contains material in quotation marks the source of which is not identified. Immunex denies the second sentence of Paragraph 146 insofar as 42 C.F.R. § 405.517 contains no reference to a "ceiling" on reimbursement amounts. Immunex admits that 42 C.F.R. § 405.517 was amended on January 1, 1998, to "provide that the allowed amount would be based upon the lower of the billed charge on the Medicare claim form or 95 percent of AWP." Immunex denies any and all remaining allegations in Paragraphs 146 and 147 that pertain to it.

148. Immunex admits that the Medicare Program had publicly announced its use of the AWP as a reimbursement benchmark. Immunex states that Program Memo AB-99-63 cited in Paragraph 148 is the best evidence of its contents. Immunex denies any and all remaining allegations in Paragraph 148 that pertain to it.

149. Immunex states that Program Memo AB-99-63 cited in Paragraph 149 is the best evidence of its contents. Immunex denies any and all remaining allegations in Paragraph 149 that pertain to it.

150 & 151. Immunex admits the allegations in Paragraphs 150 and 151.

152. Immunex admits that it reports certain pricing information for its medicines to independent pharmaceutical industry publications. Immunex denies any and all remaining allegations in Paragraph 152 that pertain to it.

153 –154. The April 2003 OIG report cited in Paragraphs 153 – 154 is the best evidence of its contents, but Immunex does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized any alleged OIG finding, opinion, statement or conclusion, or that such are applicable to Immunex or are retroactive.

155. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies the remaining allegations in Paragraph 155 that pertain to it.

156 & 157. Immunex denies the existence of, and its participation in, any "scheme" cited in Paragraph 156. Immunex states that the September 28, 2000, letter from Congressman Stark to the President of Pharmaceutical Research and Manufacturers of America cited in Paragraphs 156 and 157 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have



accurately characterized the findings, opinions, statements, or conclusions of Congressman Stark, or that such are applicable to Immunex.

158 & 159. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 159. Immunex admits that some governmental agencies have conducted investigations concerning pricing in the pharmaceutical industry. Immunex denies any and all remaining allegations in Paragraphs 158 and 159 that pertain to it.

160. Immunex admits that on occasion prior to July 1995 it provided suggested AWP's for its medicines to independent pharmaceutical industry publications. Immunex denies any and all remaining allegations in Paragraph 160 that pertain to it.

161 – 184. Immunex denies the existence of, and its participation in, any "scheme" as alleged in Paragraph 163. Immunex denies the remaining allegations in Paragraphs 161 – 184 that pertain to it.

185. Immunex admits that Plaintiffs purport to quote from an unidentified "industry consultant" as alleged in Paragraph 185, but Immunex denies any allegations suggested by the quoted material.

186 – 191. Immunex states that the *Red Book* and the unidentified DOJ report cited in Paragraph 187 and the pleadings cited in Paragraphs 189 and 190 and subparts, are the best evidence of their contents, but does not admit that the contents were accurate when created. To the extent the allegations in Paragraphs 186 – 191 and subparts are deemed to include allegations against Immunex, Immunex denies them.

192. Immunex states that the 2003 CMS document cited in Paragraph 192 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized any alleged CMS finding, opinion, statement, or conclusion. Immunex admits that it sells its medicines in

competitive markets and, as such, takes steps to keep certain information relating to its medicines confidential. Immunex denies any and all remaining allegations in Paragraph 192 that pertain to it.

193 – 196. Immunex denies any allegations in Paragraphs 193 – 196 that pertain to it.

197. In response to the allegations in Paragraph 197, Immunex denies that Plaintiffs lacked inquiry or other notice of the issues associated with reliance on AWP's as a reimbursement benchmark. Immunex specifically alleges, to the contrary, that such issues were well-known for more than a decade before Plaintiffs elected to bring this suit.

198 & 199. The allegations in Paragraphs 198 and 199 state legal conclusions to which no response is required. Immunex denies any allegations in Paragraphs 198 and 199 that pertain to it.

200. Immunex denies any allegations in Paragraph 200 that pertain to it.

201 – 421. The allegations in Paragraphs 201 – 421 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 201 – 421 are deemed to include allegations against Immunex, Immunex denies them.

422. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 422. Immunex denies that it has stated "fraudulent AWP's." Immunex denies that Plaintiff is entitled to judgment or any relief and denies any other allegations in Paragraph 422 that pertain to it.

423. Immunex denies the existence of, and its participation in any "scheme" as alleged in Paragraph 423. Immunex admits that the governmental agencies listed in Paragraph 423 have conducted investigations concerning pricing in the pharmaceutical

industry and that Immunex has received and responded to requests for information.

Immunex denies any and all remaining allegations in Paragraph 423.

424. Immunex states the "internal document" cited in Paragraph 424 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the conclusions Plaintiffs have drawn from the document cited in Paragraph 424 are accurate and denies any and all remaining allegations in Paragraph 424.

425. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported class period. Immunex admits that on occasion prior to July 1995 it reported suggested AWP's to independent pharmaceutical industry publications. Immunex states that the October 26, 2000, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized the letter. Immunex states that the interview cited in document IAWP003071 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that the conclusions Plaintiffs have drawn from the documents cited in Paragraph 425 are accurate and denies any and all remaining allegations in Paragraph 425.

426. Immunex states that the January 12, 1996, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex states that the January 12, 1995, letter is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex admits that it reported certain pricing and reimbursement information for its medicines to independent pharmaceutical industry publications during the purported class period. Immunex admits that on occasion prior to July 1995 it reported suggested AWP's to independent pharmaceutical industry publications.

Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 426 and denies any and all remaining allegations in Paragraph 426.

427. Immunex admits that it understood that AWP was a reimbursement benchmark. Immunex states that "internal documents" IAWP012961 and IAWP051149-52 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 427 and denies any and all remaining allegations in Paragraph 427.

428. Immunex states that the February 21, 1997, memo is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 428 and denies any and all remaining allegations in Paragraph 428.

429. Immunex states that documents IAWP003407-13 and IAWP016686-88 are the best evidence of their contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the documents cited in Paragraph 429 and denies any and all remaining allegations in Paragraph 429.

430. Immunex states that document IAWP005418 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the document. Immunex denies all remaining allegations in Paragraph 430..

431. Immunex admits that it distributed methotrexate sodium and leucovorin calcium in 1997 and that the AWP reimbursement benchmark for the drugs might have been higher than the actual prices paid by some customers of wholesalers. Immunex states that the DHHS Report cited in Paragraph 431 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately

characterized the DHHS Report and denies any and all remaining allegations in Paragraph 431.

432. Immunex admits that it distributed Novantrone® in 1997 and that the AWP reimbursement benchmark for the drug was higher than the actual prices that might have been paid by some customers of wholesalers. Immunex states that the DHHS 1997 Report is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized the DHHS 1997 Report and denies any and all remaining allegations in Paragraph 432.

433. Immunex admits that it produced documents pursuant to government requests. Immunex admits that Plaintiffs have reviewed such documents and that each such document is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized such documents or that such conclusions Plaintiffs have drawn are accurate and denies any and all remaining allegations in Paragraph 433.

434. Immunex denies the allegations in Paragraph 434.

435. Immunex states that document IAWP016524 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies any conclusions Plaintiffs have drawn from the document cited in Paragraph 435 and denies any and all remaining allegations in Paragraph 435.

436 – 540. The allegations in Paragraphs 436 – 540 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 436 – 540 are deemed to include allegations against Immunex, Immunex denies them.

541. Immunex denies the allegations in Paragraph 541.

542 – 594. The allegations in Paragraphs 542 – 594 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 542 – 594 are deemed to include allegations against Immunex, Immunex denies them.

595 – 598. Immunex admits that Plaintiffs purport to bring this action as alleged in Paragraphs 595 – 598, but Immunex denies that Plaintiffs are entitled to maintain this action in the manner alleged. Immunex denies that Plaintiffs or any putative class members have suffered damages as alleged in Paragraph 598. Immunex denies any and all remaining allegations of Paragraphs 595 – 598 that pertain to it.

599 – 603. The allegations in Paragraphs 599 – 603 state legal conclusions to which no answer is required. Immunex denies, however, that Plaintiffs have pled a proper class or named proper class representatives. Immunex denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraph 603.

604 – 618. The allegations in Paragraphs 604 – 618 are directed to other defendants and require no response from Immunex. To the extent allegations in those paragraphs are deemed to include allegations against Immunex, Immunex denies them.

619 – 646. The Court dismissed Count I in its Order dated February 24, 2004. Accordingly, Immunex does not respond to Paragraphs 619 – 646 of the AMCC. To the extent a response is required, Immunex denies all allegations contained within Count I of the AMCC.

647. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 646 in answering Paragraph 647.

648. Immunex admits that Plaintiffs purport to bring this action and to seek relief under Count II of the AMCC as alleged in Paragraph 648, but Immunex denies that Plaintiffs are entitled to maintain this action as alleged. Immunex denies that Plaintiffs are entitled to

any relief against Immunex under Count II of the AMCC. Immunex denies any remaining allegations in Paragraph 648.

649. The allegations in Paragraph 649 state a legal conclusion to which no answer is required. Immunex denies, however, that Plaintiffs have pled a proper class.

650. To the extent the allegations in Paragraph 650 and its subparts state legal conclusions, no answer is required. Immunex is without knowledge or information sufficient to form a belief as to the accuracy of the remaining allegations in Paragraph 650 and subparts and therefore denies those allegations.

651 – 655. Immunex denies the existence of, or its participation in, any "enterprise," "AWP Scheme," or "hidden profit-making scheme" as alleged in Paragraphs 651 – 655. Immunex states that the unidentified "industry report" cited in Paragraph 655 is the best evidence of its contents, but does not admit that the contents were accurate when created. Immunex denies that Plaintiffs have accurately characterized any alleged "industry report" finding, opinion, statement or conclusion. Immunex denies any remaining allegations in Paragraphs 651 – 655 that pertain to it.

656 – 678. Immunex denies the existence of, or its participation in, any "enterprise," "AWP Scheme," "The Immunex Manufacturer-PBM Enterprise" and/or "Manufacturer-PBM Enterprise" as alleged in Paragraphs 656 – 678 and their subparts. Immunex denies any existence of, or its participation in any operation or conduct for "criminal purposes" as alleged in Paragraph 661(m). To the extent the allegations in Paragraphs 656 – 678 and their subparts include any allegations against Immunex, Immunex denies them.

679. The allegations in Paragraph 679 state legal conclusions to which no response is required. To the extent a response is required, Immunex denies the allegations in Paragraph 679.

680. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 679 in answering Paragraph 680.

681. The allegations in Paragraph 681 state legal conclusions to which no response is required. To the extent a response is required, Immunex denies that Plaintiffs have standing to bring this action, and denies that an actual case and controversy exists. Immunex denies that setting stated reimbursement prices above the actual average wholesale price for AWPIDs is unlawful and denies any remaining allegations in Paragraph 681 that pertain to it.

682 & 683. Immunex realleges and incorporates its responses to the allegations in Paragraph 681 in answering the first sentence of Paragraph 682. Immunex denies that it "exploit[s] the Medicare reimbursement system." Immunex denies the remaining allegations in Paragraphs 682 and 683 that pertain to it. If the Court determines a legally enforceable definition of AWP that varies from historical practice, that definition should be prospective only.

684. Immunex realleges and incorporates its responses to the allegations in Paragraphs 1 – 683 in answering Paragraph 684.

685. Immunex admits that Plaintiffs purport to bring this action and to seek relief under Count IV of the AMCC as alleged in Paragraph 685, but Immunex denies that Plaintiffs are entitled maintain this action as alleged or to any relief against Immunex under Count IV. Immunex denies the remaining allegations in Paragraph 685.

686. Immunex admits that its principal place of business at the commencement of this action is Seattle, Washington. Immunex admits that certain states have enacted



consumer protection laws, but Immunex denies that such laws apply, that it has violated such laws, or that Plaintiffs or any putative class members are entitled to relief under such laws. Immunex denies any remaining allegations in Paragraph 686 and subparts that pertain to it.

687 – 691. Immunex denies the existence of, and its participation in, any "AWP Scheme" as alleged in Paragraph 687. Immunex denies any remaining allegations in Paragraphs 687 – 691 and subparts that pertain to it. Immunex further denies that Plaintiffs or any putative class members have suffered damages or injuries as alleged in Paragraphs 689 – 691.

692 – 725. Counts V to VIII and the allegations in Paragraphs 693 – 725 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 692 – 725 are deemed to include allegations against Immunex, Immunex denies them.

726 – 733. Count IX and the allegations in Paragraphs 726 – 733 are brought only by Plaintiff CMHV, which does not allege that it purchased any Immunex product and require no response from Immunex. To the extent allegations in Paragraphs 726 – 733 are deemed to include allegations against Immunex, Immunex denies them. In particular, Immunex denies the existence of, and its participation in, any "scheme," "AWP Scheme," "conspiracy" or "The Immunex Manufacturer-PBM Conspiracies."

734 – 741. Count X and the allegations in Paragraphs 735 – 741 are directed to other defendants and require no response from Immunex. To the extent allegations in Paragraphs 734 – 741 are deemed to include allegations against Immunex, Immunex denies them.

## **DEFENSES**

Without assuming any burden that it would not otherwise have, and without waiving any denial above, Immunex further responds to the AMCC by alleging the following:

1. The Complaint fails to state a claim upon which relief may be granted.
2. Immunex has not acted in a manner that is illegal, oppressive, or fraudulent and in fact acted in good faith, with just cause, and in accordance with established industry practices and government requirements and policies.
3. The federal government adopted AWP as a reimbursement benchmark with knowledge that it was not a calculation of actual average prices and with no express or implicit definition contrary to industry practice. For public policy and other reasons, the federal government retained AWP as a reimbursement benchmark in the face of years of criticism that it was not a calculation of actual average prices. Among the defenses that arise from those and other relevant circumstances are the following:
  - A. Plaintiffs' claims are barred, in whole or in part, by the political question, separation of powers, and filed rate doctrines. The relief sought by plaintiffs would interfere with legislative decisions and functions.
  - B. Plaintiffs' claims are barred, in whole or in part, because Immunex has complied with all applicable statutes and regulations.
  - C. Plaintiffs' claims are barred, in whole or in part, because they violate Immunex' rights under the Due Process and Ex Post Facto clauses of the United States Constitution, as well as all applicable state constitutions, insofar, among other things, as Plaintiffs and the putative class members

seek to impose liability under vague or nonexistent standards or retroactively for conduct that was not actionable at the time it occurred.

D. Plaintiffs' claims are barred, in whole or in part, because Immunex did not make any false statements to Plaintiffs or to any members of the putative class members. Immunex had no reasonable grounds to believe, and did not believe, that any statement was false or misleading or capable of being false or misleading.

E. The communications and conduct of Immunex and others are protected by the First Amendment, applicable state constitutions, and common law privileges, and it would violate those protections to construe the AWP practice and term of art as fraudulent.

F. Plaintiffs' claims are barred, in whole or in part, by the government contractor and similar defenses because the reimbursement system, including the use of AWP in excess of actual average prices, was designed and approved by the United States Government to serve its purposes.

G. Immunex relied on the policies and practices of the federal and state governments, and plaintiffs are estopped or otherwise barred from seeking to impose liability for such reliance.

H. Plaintiffs' approach to AWP would discourage legitimate price competition and is inconsistent with and preempted by the Sherman Act.

I. Plaintiffs' claims are barred, in whole or in part, because, inter alia, in directly or indirectly adopting "AWP" outside of its government reimbursement and industry context plaintiffs acted recklessly and assumed all risks that they or their representatives might not understand it properly,

because they are bound by the government's knowledge and purposes, and because they consented to and ratified use of AWP.

4. Plaintiffs' state law claims are preempted, in whole or in part, by federal law, including without limitation the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, the Federal Medicaid Act, regulations promulgated under those acts, and by the dormant Commerce Clause of the United States Constitution.
5. Plaintiffs' claims are barred, in whole or in part, by the *Noerr-Pennington* doctrine to the extent that such claims are premised, in whole or in part, on alleged statements or expressive conduct by Immunex, healthcare providers, or others directed at judicial, legislative, or administrative bodies of government.
6. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and repose.
7. Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, estoppel, and waiver.
8. Plaintiffs lack standing and privity.
9. Immunex denies that Plaintiffs and the putative class have met the statutory and case law requirements of state consumer protection acts. However, if such claims are found to exist, Immunex pleads all available defenses under the Acts, including standing, lack of direct purchaser, federal preemption, and lack of consumer status or involvement.
10. Plaintiffs' claims for declaratory or equitable relief are barred because plaintiffs have an adequate remedy at law, because the claims were rendered moot by

the passage of the 2003 Medicare reform legislation, and due to the doctrine of *in pari delicto* or unclean hands.

11. Plaintiffs' claims are barred, in whole or part, with respect to any alleged overcharge or supracompetitive price because third party payors passed on any effect of the alleged supracompetitive prices to their customers or employees in the form of higher premiums or in other ways; because such supracompetitive price, if any, was absorbed, in whole or part, by a person or entity that purchased the medicine directly, or by an intermediate indirect purchaser, and was not passed through to the Plaintiffs and putative class members; or because purchasers who paid directly or indirectly on the basis of an allegedly excessive AWP would have paid more with respect to this or other elements of health care pricing in the absence of AWP.
12. To the extent Plaintiffs or any member of the putative class obtain or have obtained recovery or have benefited from another entity's recovery in this or any other case or through any other method predicated on the same factual allegations, that Plaintiff or purported class member is barred from seeking recovery against Immunex based on the AMCC.
13. Plaintiffs' claims are barred, in whole or in part, to the extent that Plaintiffs and the putative class members have released, settled, entered into an accord and satisfaction, or otherwise compromised their claims.
14. Plaintiffs' and claims are barred, in whole or in part, due to their failure to join indispensable parties.

15. Plaintiffs' claims are barred, in whole or in part, because any injuries sustained by Plaintiffs or the putative class were the result of intervening or superceding conduct of third parties or of the plaintiffs or their agents or representatives.
16. Plaintiffs' claims are barred, in whole or in part, because they are speculative and remote and because of the impossibility of ascertaining and allocating of those alleged damages.
17. Plaintiffs' claims are barred, in whole or in part, because they failed to mitigate their damages, and their failure to mitigate damages should proportionately reduce the recovery of such persons and the allocation of any fault, if any exists, attributable to Immunex.
18. Plaintiffs' claims are barred, in whole or in part, because they would be unjustly enriched if allowed to recover any portion of the damages alleged in the AMCC.
19. Immunex is entitled to a set-off, should any damages be awarded against it, for the entire amount of all damages or settlement amounts recovered by Plaintiffs or the putative class, with respect to the same alleged injuries.
20. Any damages recovered by the Plaintiffs and the putative class from Immunex must be limited by any applicable statutory ceilings on recoverable damages.
21. Any punitive damages would be excessive, penal in nature, and subject Immunex to multiple and retroactive liability and deny Immunex constitutionally adequate standards, instructions, and procedures.
22. Plaintiffs' claims for punitive damages are barred by federal and state constitutions, common law, and public policies.

23. Maintenance of this action as a class action would violate the separation of powers provisions of the United States Constitution and would be an unconstitutional usurpation of authority reserved to the legislative branch.
24. Maintenance of this action as a class action and in one proceeding against many defendants would violate Immunex' rights as provided by the Federal and state constitutions by denying Immunex procedural and substantive safeguards.
25. Plaintiffs' claim for punitive and other damages against Immunex cannot be sustained because any award without the apportionment of the award separately and severally between or among the defendants and other alleged responsible parties, as determined by the alleged percentage of the wrong committed by each alleged tortfeasor, would violate Immunex' due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and would be improper under the constitutions, common law, and public policies of any applicable state.
26. Plaintiffs are not the real parties in interest.
27. Immunex maintained policies regarding samples, grants, and other issues that prohibited unlawful or questionable practices. Immunex regularly instructed relevant employees as to such policies. To the extent that Immunex had knowledge of conduct that could be viewed as improper, Immunex took prompt and reasonable steps to correct and halt such conduct, including disciplinary action against employees.
28. Immunex adopts by reference any additional applicable defense pled by any other defendant not otherwise pled in this answer. Immunex hereby gives

notice that it intends to rely upon any other and additional defense that is now or may become available or appear during, or as a result of the discovery proceedings in this action and hereby reserve its right to amend its answer to assert such defense. Immunex also reserves the right to assert such other and related defenses as may become available in the event of a determination that the action, or some part of it, is governed by the substantive law of a state other than California, Delaware, Florida, Illinois, Louisiana, Minnesota, New Jersey, New York, Pennsylvania, Texas, and Washington.

**PRAYER FOR RELIEF**

WHEREFORE, Defendant Immunex Corporation requests the following relief:

- A. Dismissal of Plaintiffs' claims with prejudice;
- B. An award of attorneys' fees and costs; and
- C. Such other legal and equitable relief as the Court deems proper.

DATED this 9<sup>th</sup> day of April, 2004.

/s/ Gary M. Ronan  
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